



# FILE COPY

August 30, 2001

Kenneth E. Brody  
Pennsylvania Department of Health  
Room 825, Health and Welfare Building  
Commonwealth Avenue and Forster Street  
P.O. Box 90  
Harrisburg, PA 17108

Dear Mr. Brody:

Your petition requesting the Food and Drug Administration to issue an advisory opinion on whether FDA regulations on medical devices do not preempt a Pennsylvania regulation that permits laboratories to accept human specimens for testing only upon request by a member of the healing arts or other person designated by statute, which does not include a health care consumer, was received by this office on 08/30/01. It was assigned docket number 01A-0375/AP 1 and it was filed on 08/30/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Jennie Butler", is written over the typed name.

Jennie Butler  
Dockets Management Branch

01A-0375

ACK 1